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Atty. Docket No.: P66431US0

REMARKS

The Office Action mailed January 29, 2004, has been carefully reviewed and in view of the Final status thereof, a Request for Continued Examination is being filed concurrently herewith. By this Amendment, Applicants have amended claims 1 and 11 and added claims 21-26. Claims 1-26 are pending in the application.

The Examiner rejected claims 1, 11 and 14 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,230,115 to Walz, Jr. et al. ("Walz"), and rejected claims 2-10, 12, 13 and 15-20 under 35 U.S.C. 103(a) as being unpatentable over Walz in view of WO 97/26937 to Israelsson et al.

As clarified in amended claim 1, the present invention is directed to a catheter set including a catheter and a package for storing of the catheter before use and for collecting or discharging urine. The package includes an elongated part forming a tube that accommodates the proximal part of the catheter which is adapted to be inserted into the urethra. A tubular distal part of the catheter remains within the package and is at least as long as the length of the elongated part of the package so as to extend through such length to prevent blocking thereof during use. In addition to separating the

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proximal and distal parts, the sealing part provides a seal between the catheter and the elongated part of the package so that urine is prevented from passing through the tube and spilling during use (see the specification at page 1, last paragraph, identifying the known problem of spillage, and at page 3, lines 25-26, noting the solution of such problem by the present invention). This is not shown or suggested by the prior art.

Walz discloses a catheterization unit having a container 24 with a pair of truncated chevrons 32 provided intermediate its length to form a restricted medially disposed opening 34 that provides communication between an upper chamber 38 and a lower chamber 36 (see column 3, lines 27-33). The catheter 22 is initially housed in the lower chamber. The restricted opening is provided with a substantially rigid tubular guide means 60 to assist in manipulation of the catheter. The guide means 60 has an internal bore 62 as well as port means 64 opening through the side walls to communicate with the internal bore 62.

To use the Walz unit, a transverse frangible portion 40 at the upper edge of the container is torn to expose the open mouth of the upper chamber. The penis glans is received within

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the upper chamber to allow the urethra to be aligned with the medially located restricted opening 34. Using the port means 64, the user grips the catheter through the flexible walls of the container to position and move the catheter axially for insertion thereof within the patient's bladder (column 4, lines 11-61).

As just set forth, the catheter is, and must be, movable relative to the guide means. Furthermore, once catheterization is complete, there is sufficient clearance between the outside wall of the catheter and the internal bore 62 to allow the container to be emptied therethrough (column 4, line 67 to column 5, line 1, noting the optional nature of feeding the catheter downwardly until it clears the bore in order to expedite the emptying process). To further facilitate the evacuation of the container, the guide means may be provided with internal splines or grooves which provide additional clearance for the passage of liquids around the outside diameter of the catheter (column 6, line 62 to column 7, line 9).

With respect to the Walz embodiment shown in Figure 18, which is relied upon by the Examiner, the guide means 110 is removable so that the entire space between the chevrons may be made available for evacuation of the fluid in the container (column 7, lines 10-26). In this embodiment, the catheter is

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pulled upwardly until the larger tubular portion thereof abuts against the guide means and, with continued axial pressure on the catheter, the guide means is released from the chevrons as shown in Figure 19. Nevertheless, as shown by the dotted lines in Figure 18 and taught consistently throughout Walz, the guide means 110 *does not provide a seal that prevents liquid from passing between the outside diameter of the catheter and the inner diameter of the guide means*. Rather, Walz is concerned with the opposite problem, namely how to increase the rate at which the container may be emptied using at least the existing clearance between these elements.

With the present invention, by contrast, the abutment between the sealing part of the catheter and the elongated portion of the package forms a seal so that urine is prevented from leaking between the outer surface of the sealing part and the inner surface of the elongated portion. Hence, urine passage through the tube formed by the elongated portion is limited to that urine being specifically directed through the inner diameter of the catheter, preventing spills during use (page 3, lines 25-26). For at least the foregoing reasons, claim 1 is distinguishable over the prior art. Favorable reconsideration is requested.

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As clarified in claim 11, the sealing part is also distinguishable over the guide means of Walz in that, unlike the latter which is movable relative to the catheter, the sealing part of the present invention separates the proximal and distal parts of the catheter at a fixed location thereon as is shown in Figures 1-3 and 5. As illustrated in these embodiments, the proximal and distal parts are distinct and, as shown in Figure 2, when in use the distal part remains within the package and extends through the length of the elongated part, while the sealing part provides a secure closure of the external opening of the elongated part. This fixed location of the sealing part is completely contrary to the adjustability of the catheter within the guide means as taught by and required for the effective use of Walz.

Therefore, for at least the foregoing reasons, claim 11 is patentable over the prior art and allowance thereof is requested. Claims 2-10 and 12-20, as well as new claims 21-26, are also in condition for allowance as claims properly dependent on an allowable base claim and for the subject matter set forth therein.

With particular respect to the new claims, claim 21 is directed to the fixed location of the sealing part and claim 25

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is directed to the sealing effected by the sealing part; these claims are allowable for the same reasons already discussed in connection with claims 11 and 1, respectively.

As set forth in claims 22 and 26, and as clearly shown in Figures 1-3 forming part of the present disclosure, the exterior opening of the elongated portion is concurrent with an open edge of the package. The seal is therefore formed adjacent the exterior opening when the sealing part is brought into abutment with the inner walls of the elongated portion. This is unlike the structure of Walz in which the narrowed area formed by the chevrons is *medially located* within the container so that the exit area of such narrowed portion is not concurrent with the open edge of the container, but instead opens into the bottom of the upper chamber. Furthermore, Walz effectively teaches against a configuration in which the exterior opening of the elongated narrow portion is concurrent with an open edge of the package as this would require elimination of the upper chamber for receiving the penis glans, which is the first advantageous feature identified in the Walz invention summary (column 1, lines 47-55). Accordingly, favorable consideration of claims 22 and 26 is requested.

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Claims 23 and 24 are directed to alternatives for manufacture, neither of which is shown by Walz nor within the realm of modification of Walz. Specifically, the production of the proximal, distal and sealing parts as an integrated unit (see the specification at page 5, lines 25-28), and the connection of a separate tubular part to the catheter (see the specification at page 4, lines 22-23; page 7, lines 25-27) are inconsistent with the relationship between the catheter and the guide means taught by Walz and beyond any reasonable modification thereof.

Accordingly, with this amendment and the foregoing remarks, entry of which is proper in conjunction with the RCE filed herewith, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any questions or comments, the Examiner is cordially invited to telephone the undersigned attorney so that the present application can receive an early Notice of Allowance.

Respectfully submitted,

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